

REMARKS/ARGUMENTS

Claims 11-20 and 22 were examined. Claims 2-10, 21, 23 and 24 were previously withdrawn pursuant to a requirement for restriction. The claims have been amended as noted above. Reexamination and reconsideration of the claims as amended are respectfully requested.

Claim Rejections - 35 U.S.C. §112

Claim 13 was rejected for reciting the limitation "the heart region" without sufficient antecedent basis. As noted above, claim 13 has been amended to overcome the rejection and also to more clearly point out its claimed subject matter. Claim 13 as amended depends on claim 12 which recites the limitation "region of infarcted tissues" from which "the [[heart]] region" of claim 13 draws antecedent basis.

Claim Rejections - 35 U.S.C. §102(e)

Claims 11 and claims 13, 18, 19, and 22 which depend thereon were rejected as being anticipated by US Patent No. 6,902,522 to Walsh et al. (hereinafter Walsh). The rejections are overcome as follows.

Independent claim 11 has been amended to recite:

*A method for treating congestive heart failure, said method comprising:
placing a band having a first end and a second end around a beating heart,
wherein the band is configured to leave a gap between the first and second ends; and
drawing the first and second ends of the band toward each other by connecting a
supporting spring member between the first and second ends of the band, the supporting spring
member spanning the gap, to provide support to a myocardial wall of the heart.*

Support for the amendments can be found throughout the original specification, particularly Figs. 2 and 7A and paragraphs 0035, 0037, 0066 and 0067.

Walsh teaches a device and method for treating cardiac diseases by securing a jacket 10 to the heart (Col. 2, Ln. 21-55). The shape of jacket 10 conforms to the external geometry of the heart. When implanted, jacket 10 completely encircles and envelops the heart,

passively constraining its end diastolic volume and preventing displacement of the papillary muscles (Col. 6, Ln. 63 - Col. 7, Ln. 20).

In rejecting the above-mentioned claims, the Examiner notes that jacket 10 can be opened along a line extending from upper end 12' to lower end 14', placed around the surface of the heart, and secured by drawing the opposing ends of the line together. Only when opposing ends of jacket 10 are joined together does it assume its intended shape, which conforms to the external geometry of the heart and achieves its therapeutic effect. Unlike the currently claimed invention, no gap is left between the opposing ends after implantation.

Walsh also fails to disclose the required "supporting spring member". Walsh uses devices from US Patent No. 5,702,343 to draw the opposing ends of jacket 10 together (Col. 8, Ln. 21-29). These devices include lateral attachment devices 22, 23, circumferential attachment device 33, suture 38, and lateral attachment device 48 which are all lace-like or sutures. Spring structures, such as springs 202, 204 of Figure 2 or the "supporting spring member" required by claim 11, are not taught or suggested.

For at least the reasons above, Walsh fails to disclose each and every element of the claims in question. Thus, the rejected claims are allowable over Walsh.

Claim Rejections - 35 U.S.C. §102(e)/§103(a)

Claims 12 and 14 were rejected as anticipated by, or in the alternative, as obvious over Walsh. The rejections are traversed in part and overcome in part as follows.

In rejecting claim 12 under 35 U.S.C. §102(e), the Examiner asserts that since Walsh's device, jacket 10, surrounds the heart, the two ends (which are attached together at implantation) are on opposite sides of infarcted tissue. Although jacket 10 can be used to treat myocardial infarction, Walsh fails to teach that the ends of the device are "located on opposite sides of a region of infarcted tissue". Walsh does not mention the treatment of any specific, localized region of infarcted tissue whatsoever. Also, the line from which jacket 10 can be opened could be located anywhere across the circumference of Walsh's device. As long as the line is closed, jacket 10 can constrain the end diastolic volume of the heart as intended. When

jacket 10 is closed, the opposing ends of the previously opened lines would be in the same location and not be on "opposite sides".

In rejecting claims 14 under 35 U.S.C. §102(e), the Examiner asserts that since jacket 10 of Walsh surrounds the heart and could be elastic (col. 11, ln.61), it is a spring element. But, Walsh fails to disclose a separate "spring under tension" between opposing ends of jacket 10. Nevertheless, claim 14 has been amended for clarification to recite:

A method as in claim 11, wherein the spring member ~~drawing~~ comprises ~~disposing~~ a spring under tension disposed between said first and second ends of the band, the band being non-distensible.

In rejecting claims 12 and 14 under 35 U.S.C. §103(a), the Examiner states that Walsh discloses the essential features of the claimed invention except for explicitly disclosing that the first and second ends of the band are on opposite sides of an infarcted region, and that the elastic element is a spring. Essentially, the Examiner agrees with the arguments above against the rejections to claims 12 and 14 under 35 U.S.C. §102(e).

However, the Examiner also asserts that it is well known in the art to provide compression bands to opposite sides of infarcted areas to reduce the replacement of infarcted tissue with scar tissue and provide mechanical stability to the dead tissue, and to provide springs to heart compression devices to allow for tight contact with the heart over the variable-volume heart cycle. The Examiner has not provided any support for his assertion. However, the motivations provided by the Examiner to provide compression bands and springs can be found in the present application ([0002], [0032], [0036], [0038], [0060]). The present invention provides a method of treating acute myocardial infarction. A region of infarcted tissue is supported by drawing two opposing sides of the region together and mechanically supporting the tissue. The infarcted region is thereby allowed to reform over time. If such provisions were so well known in the art, the devices and methods described by the present application (for example, those shown in Figs. 3A-3C and 4A-4C) would have already been explicitly disclosed or used by others prior to the present application.

Claim Rejections - 35 U.S.C. §103(a)

Claim 20, which depends on independent claim 11 through claim 18, was rejected as allegedly being obvious over Walsh. As discussed above, claim 11 is allowable over Walsh. Therefore, claim 20 is allowable as well.

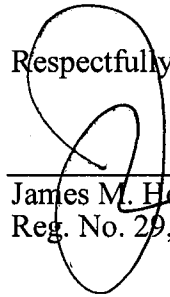
Claims 15-17 were rejected as allegedly being obvious over Walsh in view of US Patent No. 6,425,856 to Shapland (hereinafter Shapland). The Examiner states that Walsh discloses the essential features of the claimed invention except for delaying the drawing step by holding the ends apart with a biodegradable member incorporated into a spring and allowing the member to degrade, which Shapland allegedly provides. Claims 15-17 depend either directly or indirectly from independent claim 11 which has been distinguished over Walsh as mentioned above. Shapland fails to provide the missing elements from Walsh.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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Attachments
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